

**Notice of Allowability**

Application No.

09/996,288

Examiner

Stacy B Chen

Applicant(s)

YOUNG ET AL.

Art Unit

1648

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to October 14, 2003.
2. ☒ The allowed claim(s) is/are 96-98, 101, 102, 104-160 and 165-182.
3. ☒ The drawings filed on 28 November 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)          |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____             |
| 3 <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No. _____  | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment                  |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
|   | 9 <input type="checkbox"/> Other  |

### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jennifer Chheda on January 15, 2004.

The application has been amended as follows:

#### IN THE SPECIFICATION:

Page 1, line 1, delete "METHODS OF ADMINISTERING/DOSING".

Page 1, line 2, delete "FOR".

Page 1, line 3, delete "PROPHYLAXIS AND TREATMENT".

Page 4, line 31, after "SYNAGIS®," insert --(palivizumab)--.

Page 33, line 20, after "from a human antibody.", insert --The sequence identifiers for the sequences in Figures 1A and 1B are SEQ ID NO:7 and SEQ ID NO:8, respectively.--.

Page 33, line 22, after "for an antibody sequence.", insert --The sequence in Figure 2A corresponds to amino acid residues 1-106 of SEQ ID NO:231 and the sequence in Figure 2B corresponds to amino acid residues 1-120 of SEQ ID NO:208.--.

#### IN THE CLAIMS:

Cancel claims 99, 100, 103 and 161-164.

Replace claims 112-117 with the following:

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--112. An isolated antibody comprising a VL CDR2 having an amino acid sequence of SEQ ID NO: 5 and a VH CDR1 having an amino acid sequence of SEQ ID NO:10.

113. An antibody comprising a VL CDR2 having an amino acid sequence of SEQ ID NO: 5 and a VH CDR2 having an amino acid sequence of SEQ ID NO:19.

114. An antibody comprising a VL CDR2 having an amino acid sequence of SEQ ID NO: 5 and a VH CDR3 having an amino acid sequence of SEQ ID NO:20.

115. The antibody of claim 112 further comprising a VH CDR2 having an amino acid sequence of SEQ ID NO:19.

116. The antibody of claim 112 further comprising a VH CDR3 having an amino acid sequence of SEQ ID NO:20.

117. The antibody of claim 113 further comprising a VH CDR3 having an amino acid sequence of SEQ ID NO:20.--

Replace claims 133-138 with the following:

--133. The antibody of claim 112 further comprising a VL CDR3 having an amino acid sequence of SEQ ID NO: 6.

134. The antibody of claim 113 further comprising a VL CDR3 having an amino acid sequence of SEQ ID NO: 6.

135. The antibody of claim 114 further comprising a VLCDR3 having an amino acid sequence of SEQ ID NO: 6.

136. The antibody of claim 115 further comprising a VLCDR3 having an amino acid sequence of SEQ ID NO: 6.

137. The antibody of claim 116 further comprising a VL CDR3 having an amino acid sequence of SEQ ID NO: 6.

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138. The antibody of claim 117 further comprising a VL CDR 3 having an amino acid sequence of SEQ ID NO: 6.--

Replace claims 166-172 with the following:

--166. The antibody of claim 96, 97 or 98, wherein the antibody is a monoclonal antibody.

167. The antibody of claim 96, 97 or 98, wherein the antibody is a human antibody.

168. The antibody of claim 96, 97 or 98, wherein the antibody is a humanized antibody.

169. The antibody of claim 96, 97 or 98, wherein the antibody is a multispecific antibody, a chimeric antibody, a Fab fragment, a single-chain Fv or a single chain antibody.

170. The antibody of claim 96, 97 or 98, wherein the antibody is conjugated to a therapeutic or drug moiety.

171. The antibody of claim 96, 97 or 98, wherein the antibody is conjugated to a detectable substance.

172. A pharmaceutical composition comprising the antibody of claim 96, 97 or 98 and a carrier or excipient.--

Replace claims 178-180 with the following:

--178. A lyophilized formulation comprising the antibody of claim 96, 97, or 98.

179. A liquid formulation comprising the antibody of claim 96, 97, or 98.

180. A kit comprising the antibody of claim 96, 97, or 98 in one or more containers, and instructions for use.--

***Reasons for Allowance***

2. The following is an examiner's statement of reasons for allowance:

The changes to the title of the invention were made in order to reflect the subject matter of the allowable claims. The purpose of inserting "palivizumab" into the specification was to cite the generic name of the antibody product, SYNAGIS®. SEQ ID numbers were inserted to identify the sequences in the figures. The amendments to the claims were made to correct claim dependencies. Note: For clarification, the antibody claimed in claim 165, A4B4L1FR-S28R, comprises SEQ ID NOS: 48, 10, 19, 20, 11, 39, 5 and 6, as shown in the specification in Table 2, page 52, first row.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


***Conclusion***

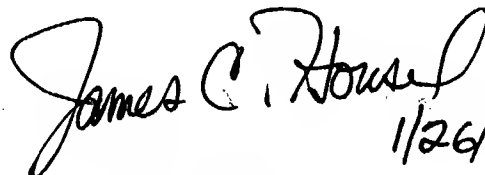
3. Claims 96-98, 101-102, 104-160 and 165-182 as amended above are allowable.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 872-9306. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy B. Chen, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday from 7:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Stacy B. Chen  
January 15, 2004

  
JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
1/26/04